

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 06-230 (GMS)
)	
APOTEX, INC.,)	
)	
Defendant.)	
)	

**MERCK'S OPPOSITION TO APOTEX'S
MOTION FOR LEAVE TO FILE A SURREPLY**

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Dated: October 13, 2006

INTRODUCTION

Plaintiff Merck & Co., Inc. (“Merck”) submits this opposition to Apotex’s Motion for Leave to File a Surreply (D.I. 26). Merck asks that the Court deny Apotex’s Motion as improper because: (1) Merck’s Reply Brief (D.I. 21) did not raise new matter that should have been in Merck’s motion and Apotex could have made its arguments (to the extent they are new) in its Answering Brief; (2) Apotex’s surreply would rehash arguments in its Answering Brief; (3) the Hatch-Waxman 30-month stay is no longer in effect upon a substantive determination of no cause of action (as here, if the Court grants Merck’s motion to dismiss) and, therefore, Apotex cannot invoke an exception based on collateral consequences; (4) no case or controversy exists with respect to Apotex’s suppliers and customers; and (5) Federal Circuit law divesting a district court of jurisdiction when a patentee grants a potential infringer a covenant not to sue remains intact after the Supreme Court’s denial of certiorari in *Apotex Inc. v. Pfizer Inc.*

ARGUMENT

I. APOTEX’S PREFERRED SURREPLY IS IMPROPER

Merck’s Reply Brief did not include matter that should have been presented in a full and fair opening brief (*see* Local Rule 7.1.(c)(2)) and Apotex does not suggest otherwise. Nor does Apotex have new authority to bring to the Court’s attention (*see* Local Rule 7.1.(c)). Thus, there is no basis for a surreply brief under the local rules or otherwise. Apotex is merely trying to get another bite of the apple, to which Merck would then have no right of response.

Apotex’s proposed surreply would make two arguments: that “the collateral consequences faced by Apotex are a direct result of Merck’s actions;” and that

“Merck’s covenant not to sue does not eliminate the controversy because it does not protect Apotex’s suppliers and customers” (D.I. 26, Exh. A, at 1, 5 argument headings). Both these arguments, to the extent they were not already made, should have been made in Apotex’s Answering Brief In Opposition To Merck’s Motion to Dismiss (D.I. 19).

Apotex’s Answering Brief raised the collateral consequences doctrine as a defense to Merck’s motion and contained a lengthy discussion of the Hatch-Waxman declaratory judgment scheme and how it allegedly relates to the issue of collateral consequences (Ans. Br. at 3-14). Apotex specifically argued that, because this is a Hatch-Waxman case, Merck’s action in dismissing the case would cause the collateral consequence of depriving Apotex of a “triggering event” (*id.* at 9). Merck’s Reply Brief contested that claim – arguing that the Hatch-Waxman scheme, not action by Merck, created any perceived injury to Apotex. All Apotex’s surreply would do is replough the same ground that Merck’s action in dismissing the case allegedly caused collateral injury.¹ Moreover, if Apotex had more to say about the interplay of Merck’s actions and the Hatch-Waxman scheme in connection with alleged collateral injury to Apotex, Apotex should have fully made its argument in the first instance. Thus, a surreply by Apotex for this argument is not warranted.

Similarly as to its second argument (pp. 5-8), Apotex had every opportunity to argue in its Answering Brief that the case is not moot because the

¹ For example, its proposed surreply (p. 3) discusses the same case, *Spencer v. Kenna*, relied on in its Answering Brief, in describing the “test under the collateral consequences doctrine.”

covenant not to sue is not comprehensive enough to cover suppliers and customers. Apotex does not even suggest that it is responding to a new issue raised in Merck's Reply Brief.² And, Apotex's discussion of further briefing in connection with its petition for writ of certiorari hardly constitutes "subsequent authority" under Local Rule 7.1.2(c) which allows for subsequent authority to be brought to the Court's attention. Moreover, Apotex's entire argument on this point is moot, because the Supreme Court has now denied the writ (Exhibit A, attached).

Apotex's motion should therefore be denied because it runs afoul of the local rules which are meant, among other things, to maintain an orderly and fair briefing process which does not over burden the Court or parties with excessive or unnecessary filings.

II. THE COLLATERAL CONSEQUENCES DOCTRINE DOES NOT APPLY AND CANNOT SUPPORT THE COURT'S CONTINUED JURISDICTION.

Contrary to Apotex's assertion, the 30-month stay is not a collateral consequence that would support the Court's continued jurisdiction. Under the 2003 Amendments to the Hatch-Waxman Act, the 30-month stay is no longer in effect "if before the expiration of such period the district court decided that the patent is invalid or not infringed (*including any substantive determination that there is no cause of action for patent infringement or invalidity*) . . ." 21 U.S.C. §355(j)(5)(B)(iii) (emphasis added).

² Apotex filed its Motion for Leave over three weeks after Merck's Reply Brief was served. This lengthy delay is further evidence that its proposed surreply was not necessitated by Merck's Reply Brief.

Merck's covenant not to sue, along with a dismissal with prejudice as Merck requests, would eliminate any cause of action for patent infringement of the patents at issue. This Court's grant of Merck's motion to dismiss this case (with prejudice) for lack of subject matter jurisdiction based on Merck's covenant not to sue would certainly effect a "substantive determination of no cause of action for infringement or invalidity." Thus, the 30-month stay will no longer be in effect.

Apotex has no injury that would support the Court's continued jurisdiction. After dismissal with prejudice, Apotex will be placed in the same position it was in before Merck filed this suit. Simply put, Apotex will have to wait for the companies that were the first to file their Paragraph IV certifications against Merck's patents (apparently, Barr Laboratories, Inc. and Teva Pharmaceuticals USA, Inc.) to begin selling their products and receive their 180-day statutorily granted exclusivity. *See Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005); *see also Merck & Co. Inc. v. Barr Labs., Inc.*, Case No. 01-CV-8223 (S.D.N.Y.). Apotex is attempting to scheme the Hatch-Waxman Act, not to right a wrong it has suffered, and to usurp Barr's and Teva's rights by forcing the start of their 180-day exclusivity period.

III. THE U.S. SUPREME COURT'S RECENT DENIAL OF CERTIORARI IN *APOTEX INC. V. PFIZER* SUPPORTS THAT THERE IS NO CASE OR CONTROVERSY.

Apotex has not met its burden to prove that a case or controversy remains that would support the Court's continuing subject matter jurisdiction. Apotex contends that this case is similar to that of *Apotex, Inc. v. Pfizer Inc.*, where, in a petition for certiorari to the Supreme Court, Apotex challenges the Federal Circuit's "reasonable

apprehension” test as applied to the Hatch-Waxman Act framework. *Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp 2d 187 (S.D.N.Y. 2005), *aff’d*, 159 Fed. Appx. 1013 (Fed. Cir. 2005), *petition for cert. filed*, 74 U.S.L.W. 3476 (U.S. Feb. 9, 2006) (No. 05-1006). Apotex’s surreply would argue that, if the Supreme Court found that *Pfizer* was not moot, this Court should find in favor of Apotex in the case at bar for similar reasons (surreply at 6). Three days ago, however, the Supreme Court denied Apotex’s petition for certiorari in *Pfizer*, rendering Apotex’s arguments untenable. See Supreme Court Order List: 549 U.S., Tuesday, Oct. 10, 2006, at 12, attached as Exhibit A.

In *Pfizer*, Apotex filed a Paragraph IV certification listing a number of Pfizer’s patents. *Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp 2d 187 (S.D.N.Y. 2005). When Pfizer did not file a patent infringement action within the 45-day window, Apotex filed a declaratory judgment action, arguing a reasonable apprehension of suit, which was dismissed for lack of subject matter jurisdiction. *Id.* The Federal Circuit affirmed. 159 Fed. Appx. 1013 (Fed. Cir. 2005). Apotex then filed a petition for certiorari challenging the Federal Circuit’s affirmance, and, specifically, the application of the Federal Circuit’s two-part “reasonable apprehension” test to the Hatch-Waxman declaratory judgment mechanism.

On October 10, 2006, the Supreme Court denied Apotex’s petition for certiorari, leaving the Federal Circuit’s application of its two-part “reasonable apprehension” test intact. Thus, as the Federal Circuit held in *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, a patentee may divest a court of subject matter jurisdiction over an accused infringer’s declaratory judgment action by covenanting not to sue the accused

infringer for infringement because the accused infringer no longer had a reasonable apprehension of being sued. 57 F.3d 1054 (Fed. Cir. 1995).

Apotex's surreply contends that a case or controversy still exists because Merck's covenant not to sue would not protect Apotex's putative, future customers from patent infringement liability. Apotex is wrong. Any alleged threat to Apotex's customers does not create a controversy of "sufficient immediacy" that would support continued jurisdiction. *See Maryland Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273, 61 S. Ct. 510, 85 L. Ed. 826 (1941). There is no present or future threat to Apotex's customers of a patent infringement suit by Merck. First, Apotex currently has no customers for the generic drug at issue, and in a best case scenario, would not have any customers until 2008. Second, Merck has neither indicated nor implied that it would sue any Apotex customers for patent infringement in the future. Indeed, many future customers of Apotex are also potential customers of Merck, making it highly improbable that Merck would sue those customers for patent infringement. Thus, any apprehension that Merck would sue Apotex's future customers for patent infringement is not "reasonable" and is too attenuated to maintain a case or controversy.

CONCLUSION

For all the reasons set forth above and in Merck's Motion to Dismiss, and just as this Court recently held in *Watson*, Apotex's Motion For Leave to File a Surreply should be denied and Merck's Motion to Dismiss should be granted.

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Dated: October 13, 2006
541401

CERTIFICATE OF SERVICE

I hereby certify that on October 13, 2006, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

Richard L. Horwitz, Esquire
POTTER ANDERSON & CORROON LLP
Hercules Plaza, 6th Floor
1313 North Market Street
Wilmington, DE 19899

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on October 13, 2006 upon the following individuals in the manner indicated:

BY E-MAIL AND HAND DELIVERY

Richard L. Horwitz, Esquire
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120 South Riverside Plaza; 22nd Floor
Chicago, IL 60606

/s/ Mary B. Graham

Mary B. Graham (#2256)

EXHIBIT A

(ORDER LIST: 549 U.S.)

TUESDAY, OCTOBER 10, 2006

ORDERS IN PENDING CASES

06M25 ROBINSON, JOE L. V. FREEDOM FAITH MISSIONARY, ET AL.

The motion to direct the Clerk to file a petition for a writ of certiorari out of time under Rule 14.5 is denied.

06M26 WIMMER, JOHN T. V. HEWLETT-PACKARD CO.

The motion to direct the Clerk to file a petition for a writ of certiorari out of time is denied. The Chief Justice took no part in the consideration or decision of this motion.

06M27 BELLANICH, JOHN D. V. DOE, JOHN

06M28 BAUMGARTEN, BARBARA A. V. NY DEPT. OF PROTECTIVE SERVICES

06M29 WHITE, FRED V. QUARTERMAN, DIR., TX DCJ

06M30 DAGO, GEORGE E. V. UNITED STATES

The motions to direct the Clerk to file petitions for writs of certiorari out of time are denied.

134, ORIG. NEW JERSEY V. DELAWARE

The motion of Special Master for allowance of fees and disbursements is granted, and the Special Master is awarded a total of \$65,532.12 for the period January 23, 2006, through August 31, 2006, to be paid equally by the parties.

05-380 GONZALES, ATT'Y GEN. V. CARHART, LEROY, ET AL.

The motion of Religious Coalition for Reproductive Choice, et al. for leave to file a brief as *amicus curiae* out of time is granted. The motion of Institute for Reproductive Health Access and Fifty-Two Clinics and Organizations for leave to file a

06-6366 AVILA, PRIMATIVO V. UNITED STATES

06-6368 BANKS, FREDERICK H. V. UNITED STATES

06-6369 ALLEN, LAMONT V. UNITED STATES

The petitions for writs of certiorari are denied.

05-1006 APOTEX INC., ET AL. V. PFIZER, INC.

The petition for a writ of certiorari is denied. The Chief Justice took no part in the consideration or decision of this petition.

05-1285 MORRIS, THOMAS L., ET AL. V. TANNER, JUDGE, ET AL.

The motion of Mountain States Legal Foundation for leave to file a brief as *amicus curiae* is granted. The petition for a writ of certiorari is denied.

06-145 ADAMS, ALLEN D., ET AL. V. PENSION BENEFIT GUARANTY CORP.

The petition for a writ of certiorari is denied. The Chief Justice took no part in the consideration or decision of this petition.

06-162 CANO, SANDRA V. BAKER, ATT'Y GEN. OF GA, ET AL.

The motion of Suzanne Besser, et al. for leave to file a brief as *amici curiae* is granted. The motion of J. Budziszewski for leave to file a brief as *amicus curiae* is granted. The motion of Texas Black Americans for Life and L.E.A.R.N, et al. for leave to file a brief as *amici curiae* is granted. The motion of Nuturing Network, et al. for leave to file a brief as *amici curiae* is granted. The petition for a writ of certiorari is denied.

06-164 MAY, RAYMOND D., ET AL. V. BP WEST COAST PRODUCTS LLC

The petition for a writ of certiorari is denied. Justice Breyer took no part in the consideration or decision of this